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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/139,425	08/25/1998	CHARLES T. ESMON	OMRF-171	5290

7590

04/19/2002

Holland & Knight LLP
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EXAMINER

SANDALS, WILLIAM O

ART UNIT

PAPER NUMBER

1636

DATE MAILED: 04/19/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory ActionApplication No.
09/139,425Applicant(s)
Esmon et al.Examiner
William SandalsArt Unit
1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED Apr 10, 2002 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid the abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

THE PERIOD FOR REPLY [check only a) or b)]

- a) ☒ The period for reply expires 6 months from the mailing date of the final rejection.
- b) ☐ In view of the early submission of the proposed reply (within two months as set forth in MPEP § 706.07 (f)), the period for reply expires on the mailing date of this Advisory Action, OR continues to run from the mailing date of the final rejection, whichever is later. In no event, however, will the statutory period for the reply expire later than SIX MONTHS from the mailing date of the final rejection.

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☒ A Notice of Appeal was filed on Feb 27, 2002. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☒ The proposed amendment(s) will be entered upon the timely submission of a Notice of Appeal and Appeal Brief with requisite fees.
3. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search. (See NOTE below);
- (b) ☐ they raise the issue of new matter. (See NOTE below);
- (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without cancelling a corresponding number of finally rejected claims.

NOTE: _____

4. ☒ Applicant's reply has overcome the following rejection(s):
Claims 7 and 19 rejected under 35 USC 112, first and second paragraph.
5. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment cancelling the non-allowable claim(s).
6. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because:
See attached.
7. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
8. ☒ For purposes of Appeal, the status of the claim(s) is as follows (see attached written explanation, if any):
Claim(s) allowed: 1-4 and 7-11
Claim(s) objected to: 14, 15, and 21-25
Claim(s) rejected: 5, 6, 12, 13, and 16-20
9. ☐ The proposed drawing correction filed on _____ a) ☐ has b) ☐ has not been approved by the Examiner.
10. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
11. ☐ Other: _____

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DEA/FCE-1994

SERIAL NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
09/139,425			

EXAMINER	
W. Sandals	
ART UNIT	PAPER NUMBER
1636	23

DATE MAILED:

Please find below a communication from the EXAMINER in charge of this application

Commissioner of Patents

1. Amendments to the claims in Paper No. 21 have overcome the rejection of the claims under 35 USC 112, second paragraph in the previous office action, and the rejection is withdrawn.
2. Amendments to claims 7 and 19 in Paper No. 21 have overcome the rejection of the claims under 35 USC 112, first paragraph, written description, in the previous office action, and the rejection is withdrawn.
3. Arguments filed in Paper No. 21 regarding the rejection of the claims under 35 USC 112, first paragraph, scope of enablement, have been fully considered but they are not persuasive. The argument presented asserts that several successes were reported in the literature, constituting

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proof of enablement. As stated in the rejection by Anderson in a paper published in 1998, contemporary with the instant filed application, only anecdotal reports exist of patients being helped by gene therapy, and that there is no conclusive evidence of successful treatment of human disease. The argument is therefore, not found convincing.

Arguments set forth asserting the rejection of the claims under 35 USC 102 are not found convincing. Paper No. 21 asserts that US 5,254,532 teaches that the complex is formed before delivery to the large vessel endothelial cell. The claims state that an agent which binds selectively to endothelial protein C receptor (EPCR) is selected from the group consisting of protein C, activated protein C, antibodies reactive with EPCR and fragments thereof binding to EPCR, and a molecule to be delivered to a large vessel endothelial cell. US 5,254,532 taught the binding of protein C to the EPCR. Nowhere do the claims state that protein C must form a complex before binding to the EPCR. Therefore, the argument is not found convincing.

Arguments set forth in Paper No. 21 assert that the claims rejected under 35 USC 102 are drawn to a method. Claims 13, 15, 19 and 20 are drawn to a composition. The argument is therefore moot.

Arguments set forth in Paper No. 21 assert that US 5,852,171 taught that protein C binding to EPCR is non-specific. At column 7, lines 4-55 US 5,852,171 teaches that protein C binds by three distinct mechanisms, one of the mechanisms of binding involves the ability of protein C to bind to negatively charged surfaces by a non-specific mechanism. While this mechanism is non-specific, it does not relate to the binding of protein C to EPCR and it does not

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negate the specific binding of protein C to EPCR. The argument is therefore not found convincing.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to William Sandals whose telephone number is (703) 305-1982. The examiner can normally be reached on Monday through Thursday from 8:30 AM to 7:00 PM.

April 18, 2002


TERRY MCKELVEY
PRIMARY EXAMINER